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SERIES I No. 18

OFFICIAL GAZETTE



GOVERNMENT OF GOA

EXTRAORDINARY

GOVERNMENT OF GOA

Department of Public Health

Notification

13/53/87-I/PHD

In exercise of the powers conferred by section 78 read with section 10, sub-section (2) of section 71 of the Narcotic Drugs and psychotropic Substances Act, 1985 (Central Act 61 of 1985), and all other powers enabling it in this behalf, the Government of Goa hereby makes the following rules so as to amend the Goa, Daman and Diu Narcotic Drugs and Psychotropic Substances Rules, 1987, as follows:

1. *Short title and commencement.*— (1) These rules may be called the Goa Narcotic Drugs and Psychotropic Substances (Amendment) Rules, 2003.

(2) They shall come into force at once.

2. *Amendment of Rule 1.*— In rule 1 of the Goa, Daman and Diu Narcotic Drugs and Psychotropic Substances Rules, 1987 (hereinafter called the "principal Rules"),—

(i) in sub-rule (1), the figure and words, "Daman and Diu" shall be omitted;

(ii) in sub-rule (2), for the expression "Union territory of Goa, Daman and Diu", the expression "State of Goa" shall be substituted.

3. *Amendment of rule 2.*— In rule 2 of the principal Rules,—

(i) in clause (b),—

(a) in item (i), the figure and words, "Daman and Diu" shall be omitted;

(b) in item (ii), for the expression, "Drugs Controller, Directorate of Health Services", the expression "Director, Directorate of Food and Drugs Administration" shall be substituted;

(ii) for clause (c), the following shall be substituted, namely:—

"(c) "Chemical Analyser" means:—

(i) any officer not below the rank of Junior Scientific Officer of the Combined Food and Drugs Laboratory under the Directorate of Food and Drugs Administration, Government of Goa; or

(ii) the Junior Scientific Officer, Senior Scientific Officer and the Assistant Director of the Central Forensic Science Laboratory, Hyderabad;";

(iii) for clause (d), the following shall be substituted, namely:—

"(d) "Director" means the Director of the Directorate of Food and Drugs Administration, Government of Goa, who is also a Controlling Authority in terms of sub-rule (3) of rule 50 of the Drugs and Cosmetics Rules, 1945;";

(iv) in clause (g), the figure and words, "Daman and Diu" shall be omitted;

(v) for clause (j), the following shall be substituted, namely:—

"(j) 'Licensing Authority' means any officer of the Directorate of Food and Drugs Administration, not below the rank of Assistant Drugs Controller, authorised or designated as such by the Director of the Directorate of Food and Drugs Administration, by an order published in the Official Gazette;";

(vi) in clause (n),—

(a) for the words "Medical Practitioner", the words "Registered Medical Practitioner" shall be substituted;

(b) for item (ii), the following shall be substituted, namely:—

"registered or eligible for registration in a medical register of a State meant for the registration of persons practising the modern scientific system of medicine (excluding the Homoeopathic system of medicine); or";

(c) for item (iii), the following shall be substituted, namely:—

"(iii) registered in a medical register (other than a register for the registration of Homoeopathic Practitioners) of a State, who although not falling within sub-clause (i) or sub-clause (ii) is declared by a general or special order made by the Government in this behalf as a person practising the modern scientific system of medicine for the purposes of this Act; or";

(d) in item (iv), for the expression "Union territory", the word "State" shall be substituted;

(vii) for clause (q), the following shall be substituted, namely:—

"(q) "State of Goa" means the State of Goa";

(viii) after clause (q), the following clauses shall be inserted, namely:—

"(r) "Morphine" includes any preparation containing morphine;

(s) "recognised medical institution" means a hospital or medical institution recognised for the purpose, under Chapter V-A of these Rules. It is the responsibility of the Institution so recognised to ensure that morphine obtained by them is used for medical purposes only".

4. *Amendment of rule 21.*— In rule 21 of the principal Rules, in sub-rule (1), for the expression "Drugs Controller's Office", the expression "Office of the Directorate of Food and Drugs Administration" shall be substituted.

5. *Amendment of rule 28.*— In rule 28 of the principal Rules, for the expression "Drugs Controller, Government of Goa, Daman and Diu", the expression "Director, Directorate of Food and Drugs Administration, Government of Goa" shall be substituted.

6. *Amendment of rule 43.*— In rule 43 of the principal Rules, in sub-rule (4), for the expression "Office of Drugs Controller", the expression "Directorate of Food and Drugs Administration" shall be substituted.

7. *Amendment of rule 45.*— In rule 45 of the principal Rules, for the expression "Drugs Controller's Office", the expression "Directorate of Food and Drugs Administration" shall be substituted.

8. *Amendment of rule 47.*— In rule 47 of the principal Rules, for the expression "Drugs Controller", wherever it occurs, the expression "Director, Directorate of Food and Drugs Administration" shall be substituted.

9. *Amendment of rule 48.*— In rule 48 of the principal Rules,—

(i) the figure and words, "Daman and Diu" shall be omitted;

(ii) for the expression "Union territory", the word "State" shall be substituted.

10. *Amendment of rule 50.*— In rule 50 of the principal Rules, for the expression "Union territory", the word "State" shall be substituted.

11. *Amendment of rule 51.*— In rule 51 of the principal Rules, in sub-rule (2), for the expression "Drugs Controller's Office", the expression "Office of the Directorate of Food and Drugs Administration" shall be substituted.

12. *Amendment of rules 55, 56, 57, 59 and 60.*— In rules 55, 56, 57, 59 and 60 of the principal Rules, for the expression "Drugs Controller", wherever it occurs, the expression "Director, Directorate of Food and Drugs Administration" shall be substituted.

13. *Insertion of new chapter.*— After chapter V of the principal Rules, the following chapter shall be inserted, namely:—

"CHAPTER V-A

Morphine and its preparations for alleviation of pain

64-A. *Special provision relating to use, etc. of morphine by recognised Medical Institutions.*—Notwithstanding any provision to the contrary contained in any other rule of these Rules, the possession, transport, purchase, sale, import Inter State, export Inter State or use of morphine or any preparation containing morphine in respect of a recognised medical institution shall be as per the following provisions.

64-B. *Recognition of Medical Institution.*— (1) Every medical institution which intends to be recognised for the purpose under this chapter shall apply in Form NDPS-7 hereto to the Director, who shall convey his decision thereon or recognition within three months of the receipt of the application.

(2) If it comes to the notice of the Director, that morphine obtained by the recognised medical institution was supplied or used for non-medical use or that any of the rules under this chapter is not complied with, the Director, may, for reasons to be recorded in writing, revoke the recognition accorded under these rules.

64-C *Duties of recognised Medical Institution.*— (1) Every recognised medical institution shall designate one or more Registered Medical Practitioner who may prescribe Morphine for medical purposes. When more than one qualified medical Practitioner have been designated, one of them shall be designated as overall in-charge.

(2) The designated Registered Medical Practitioner or the overall in-charge, as the case may be, shall,—

(a) endeavour to ensure that the stock of morphine is adequate for patient's need:

(b) maintain adequate security over stock of morphine:

(c) maintain a record of all receipts and disbursements of morphine in Form NDPS-8 hereto; and

(d) ensure that estimates and other relevant information required to be sent by the recognised Medical Institution under this Chapter are sent to the authorities concerned.

64-D. *Sending of estimates of requirement of morphine by the recognised Medical Institution.*— Every recognised Medical Institution shall send their annual requirement of morphine in Form NDPS-9 hereto by 30th November of the preceding year alongwith the name and address of the supplier from whom they intend to buy it, to the Director.

64-E. *Approval of estimates by the Director, Directorate of Food and Drugs Administration.*— The Director, Directorate of Food and Drugs Administration, who receives the annual requirement as aforesaid shall consider it, and may, if necessary, call for necessary clarification. A reply on approved estimates or not accepting the estimates shall be sent before the 21st of December of the preceding year. A copy of the communication shall be sent each to the supplier whose name has been given in the estimate, if the supplier is located in another State, the Drugs Controller or any other competent authority of that State, the Drugs Controller General of India and the Narcotics Commissioner of India.

64-F. *Supplementary estimates.*— If the requirement of the recognised Medical Institution exceeds the annual estimate approved by the Director, Directorate of Food and Drugs Administration, the recognised Medical Institution may send a supplementary estimate at any time to the Director, which shall be considered and dealt with by the Director in the same manner as the annual estimate.

64-G. *Supply and purchase of morphine.*— The provisions of rules in other chapters in respect of the possession, transport,

purchase, sale, import inter-State, export inter-State or use of manufactured drugs shall not apply to the possession, transport, purchase, sale, import inter-state, export inter-state, or use of morphine in respect of a recognised Medical Institution. The possession, transport, purchase, sale, import inter-State, export inter-State or use of morphine in respect of a recognised Medical Institution shall be in accordance with the following provisions,—

- (i) The recognised Medical Institution shall place orders for purchase of morphine to a manufacturer/supplier in Form NDPS-10 hereto, alongwith a photocopy of the communication of the Director vide which the Institution was recognised for the purposes of this chapter and a copy of the communication of the Director vide which the approved estimates were conveyed. A copy of the order for purchase shall be sent to the Director and the Narcotics Commissioner of India.
- (ii) The manufacturer/supplier shall send morphine to the recognised Medical Institution under this chapter only on the basis of an order for purchases received in Form NDPS-10 hereto, alongwith copies of recognition granted by the Director and the approved estimates communicated by the Director. The manufacturer/supplier shall despatch the morphine consignment alongwith a consignment note in quintuplicate in the Form NDPS-11 hereto. Copies of the consignment note shall be sent by the manufacturer/supplier to the Drugs Controller of the State in which the manufacturer/supplier is located, the Drugs Controller of the State in which the recognised Medical Institution is located and the Narcotics Commissioner of India. He shall also keep a copy of the consignment note.
- (iii) On receipt of the consignment, the recognised Medical Institution shall enter the quantity received with date in all the copies of the consignment note, retain the original consignment note, send the duplicate to the supplier, triplicate to the Director, the quadruplicate to the Drugs Controller of the State (in cases in which the consignment originated outside the

State in which the supplier is located) and the quintuplicate to the Narcotics Commissioner of India.

- 64-H. *Maintenance of records.*— All records generated under this Chapter shall be kept for a period of two years from the date of transaction which shall be open for inspection by the officers of the Directorate of Food and Drugs Administration appointed and notified under section 21 of the Drugs and Cosmetics Act, 1940 (Central Act 23 of 1940), as well as, all the officers not below the rank of the Drugs Inspectors of the Directorate of Food and Drugs Administration and notified under section 42 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (Central Act 61 of 1985) by the Government of Goa.
- 64-I. *Inspection of stocks of morphine.*— The stocks of morphine under the custody of a recognised Medical Institution shall be open for inspection by the Director or any other officer subordinate to him, who is duly appointed and notified under section 21 of the Drugs and Cosmetics Act, 1940 (Central Act 23 of 1940), as well as, all the officers not below the rank of the Drugs Inspectors of the Directorate of Food and Drugs Administration and notified under section 42 of the Narcotic Drugs and Psychotropic Substances Act, 1985, (Central Act 61 of 1985) by the Government of Goa.
- 64-J. *Appeals.*— Any Institution aggrieved by any decision of or order passed by the Director relating to recognition, revocation of recognition of any Institution or estimate may appeal to the Secretary, Government of Goa, Department of Health, within ninety days from the date of communication of such decision or order".

14. *Amendment of rule 65.*— In rule 65 of the principal Rules,— (i) for sub-rule (1), the following shall be substituted, namely:—

"(1) In cases involving the seizure of opium and other narcotic drugs, reward upto 10% of the estimated market value of the goods

involved (half of the maximum reward) indicated in the Annexure as amended from time to time, in respect of opium and other narcotic drugs and psychotropic substances alongwith fine imposed may be granted in such proportion as the Commissioner of Excise/ Director General of Police/Director of the Directorate of Food and Drugs Administration, may think fit to any official of the Excise/Police/Office of the Directorate of Food and Drugs Administration, respectively:

Provided rewards in excess of the above limit, not exceeding 20% (as shown in the Annexure and as revised from time to time) of the said value of illicit prices indicated, alongwith fine imposed may be considered in cases where the Government servant has exposed himself to great personal hazard or displayed exemplary courage, initiative, ingenuity or resourcefulness of an extraordinary character of his personal efforts have been mainly responsible for the detection of the Contraband, narcotic drugs/psychotropic substances. The prescribed purity as indicated in the Annexure will be determined after getting the potency of the seized drugs tested at the combined Food and Drugs Laboratory of the Directorate of Food and Drugs Administration, Government of Goa, or Central Forensic Science Laboratory, Hyderabad, for the payment of reward in question. However, 50% of the total amount of the reward admissible may be disbursed as soon as it is identified that the seized drug is a narcotic drug:

Provided further that rewards exceeding Rs. 50,000/- but upto Rs. 1,00,000/- shall be granted by the concerned Secretary to the Government and over Rs. 1,00,000/- shall be decided and granted by a Committee consisting of:—

- (i) the Chief Secretary;
- (ii) the Secretary of the Department;
- (iii) the Departmental Head.”;

(ii) in sub-rule (9), for the expression “Drugs Controller”, the expression “Director, Directorate of Food and Drugs Administration” shall be substituted.

15. *Amendment of rule 69.*— In rule 69 of the principal Rules, in sub-rules (1) and (2), the figure and words, “Daman and Diu” shall be omitted.

16. *Amendment of rule 70.*— In rule 70 of the principal Rules, in sub-rule (ii), for the expression “Drugs Controller”, the expression “Director, Directorate of Food and Drugs Administration” shall be substituted.

17. *Amendment of Forms.*— (i) in FORM O. P. I. appended to the principal Rules, in the ‘Conditions’, in items 2, 8(1) and 9, the figure and words, “Daman and Diu”, wherever they occur, shall be omitted;

(ii) in FORM O. P. II appended to the principal Rules, in the ‘Conditions’, in items 2, 8(1) and 10, the figure and words, “Daman and Diu”, wherever they occur, shall be omitted;

(iii) in FORM O. P. IIA appended to the principal Rules, in the ‘Conditions’, in items 2 and 9, the figure and words, “Daman and Diu”, wherever they occur, shall be omitted;

(iv) in FORM O. P. III appended to the principal Rules,—

(a) in the heading, for the expression “Union territory of Goa, Daman and Diu”, the expression “State of Goa” shall be substituted;

(b) in the ‘Conditions’, in items 3, 4(1) and 7, the figure and words, “Daman and Diu” wherever they occur, shall be omitted;

(v) in FORM – H appended to the principal Rules,—

for the expression “Drugs Controller of Goa, Daman and Diu” or “Drugs Controller, Goa, Daman and Diu” or “Drugs Controller”, wherever they occur, the expression “Director, Directorate of Food and Drugs Administration, Government of Goa” shall be substituted;

(vi) in FORM – NDPS – I appended to the principal Rules,—

(a) the figure and words, “Daman and Diu”, wherever they occur, shall be omitted;

(b) for the expression “Union territory”, the expression “State of Goa” shall be substituted;

(c) for the expression “Drugs Controller’s office”, wherever it occurs, the expression “Director, Directorate of Food and Drugs Administration” shall be substituted;

(vii) in FORM – N. D. P. S. 2 appended to the principal Rules,—

(a) in item 1, the figure and words, "Daman and Diu" shall be omitted;

(b) after clause 5, the clauses numbered as 6, 5, 6, 7, 8 and 9 shall be re-numbered as clauses 6, 7, 8, 9, 10 and 11;

(c) in clause 8 as so renumbered, for the expression "Drugs Controller's office", the expression "Office of the Director, Directorate of Food and Drugs Administration" shall be substituted;

(viii) in FORM – N. D. P. S. 3 appended to the principal Rules,—

(a) in item 2, the figure and words, "Daman and Diu" shall be omitted;

(ix) in FORM N. D. P. S. 4, appended to the principal Rules,— in PART – I, PART – II and PART – III, in the heading, for the expression "Union Territory of Goa, Daman and Diu", the expression "State of Goa" shall be substituted.

(x) in FORM N. D. P. S. 5, in PART – I, PART – II, PART – III and PART – IV, in the heading, for the expression "Union territory of Goa, Daman and Diu", the expression "State of Goa" shall be substituted;

(xi) in FORM N. D. P. S. 6, in "COUNTERFOIL", Duplicate and Triplicate, in the heading, for the expression, "Union territory of Goa, Daman and Diu", the expression, "State of Goa" shall be substituted.

18. *Insertion of new Forms.*— After FORM NDPS-6 (TRIPLICATE) in the principal Rules, the following forms shall be inserted, namely,—

"FORM N. D. P. S. - 7"

(See Rule 64-B)

(1) Name of the Institution and address:

(2) Name of the Head/Incharge of the Institution:

(3) Number of persons employed:

(i) Doctors

(ii) Nursing staff

(iii) Others

(4) Number of patients treated during the previous calendar year:

(i) Inpatient

(ii) Out-patient

(5) Whether the hospital has facilities to treat Cancer patients Yes/No

(6) Number of cancer patients treated during previous calendar year:

(i) Inpatient

(ii) Out-patient

(7) Name of the qualified Medical

Practitioner who would prescribe morphine (if there are more than one qualified Medical Practitioner who would prescribe morphine, indicate the name of the Medical Practitioner who would be overall incharge)

(8) Whether the Institution's recognition for the purpose was withdrawn earlier (if the recognition was withdrawn earlier, the details are to be given) Yes/No

Station :

Date :

Signature of the Head/Incharge
of the Institution with name

FORM N. D. P. S.-8

(See Rule 64-C)

Record of receipt, disbursement and balance of morphine

Date:

Details of quantity received				Details of quantity disbursed				Quantity in hand at the close of the day
Quantity in hand at the beginning of the day	Sr. No.	Quantity	From whom received	Consignment note, Bill of entry No.	Sr. No.	Quantity	Name of the person and address to who disbursed	Name of the Medical Practitioner who prescribed

Signature

Note:

- (1) This record is to be maintained on day to day basis and entries shall be made for each day the Institution functions. Entries shall be completed for each day before the close of the day. The authorised Medical Practitioner/In-charge or any person authorised by them shall initial after entry of each day with date. The pages of the register shall contain necessary number.
- (2) This record shall be retained for two years from the date of last entry.
- (3) This record shall be produced to the authorised officer whenever called upon on during the course of their inspection.

FORM N. D. P. S.- 9

(See Rule 64-D)

ESTIMATE OF ANNUAL REQUIREMENT

- (1) Name and address of the recognised Medical Institution.
- (2) Period for which the estimate is submitted.
- (3) Quantity disbursed during the previous year.
- (4) Quantity estimated to be disbursed during the year for which estimate is submitted.
- (5) Supplier who would supply the quantity.

Sr. No.	Name and address of the supplier	Quantity

- (6) If this is a supplementary requirement, give details of annual requirement sent earlier and the reasons for giving a supplementary requirement.

Station:

Date:

Signature of the authorised
Medical Practitioner/In-charge
with name

FORM N. D. P. S.- 10

(See Rule 64-G) (i)

ORDERS FOR PURCHASE

To,

(Name and address of the supplier)

- (1) Name and address of the recognised Medical Institution which places the order
- (2) Description of the quantity for which order is placed
- (3) Whether the Institution has been recognised by the Director of Food and Drugs Administration (A photocopy of the recognition is to accompany each order for purchase)
- (4) Whether this order is covered by the estimate approved by the Director of Food and Drugs Administration (A photocopy of the approved estimate is to accompany each order of purchase)

- (5) Details of other orders for purchase made during the year.

Sr. No.	Quantity	To whom order was placed
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Station:

Date:

(Signature of the person authorised to place order with name and designation, if any)

Note:

- (1) A copy of this order shall be kept by the recognised Medical Institution which places the order.
- (2) This shall be retained for two years from the date of transaction.

FORM N. D. P. S.- 11

(See Rule 64-G) (ii)

Serial No.

CONSIGNMENT NOTE

(To accompany a consignment of morphine)

Date and time of despatch of the consignment:

- (1) Name and address of the consignor
- (2) Name and address of the consignee, i. e. recognised Medical Institution
- (3) Description and quantity of the consignment:

Number of packages	Quantity
	Gross Net

- (4) Mode of transport (Particulars of the transporter, Registration number of the vehicle, R. R., if the transport is by railways, etc.)

Signature of the Consignor with date
(Name and designation, if any)

To be filled by consignee:

- (5) Date and time of receipt by the consignee and his remarks
- (6) Quantity received by the consignee:

Number of packages	Quantity
	Gross Net

Signature of the Consignor with date
(Name and designation, if any)

Note:

- (1) This consignment note shall be serially numbered on annual basis.
- (2) The consignor should record a certificate on the cover page of each book containing consignment notes indicating the number of pages contained in the consignment note-book.
- (3) The consignor should maintain a Register showing the details of the books of consignment note brought in use during a particular year.
- (4) Each consignment of morphine shall be accompanied by this consignment note in quintuplicate (i.e. five).
- (5) This consignment note shall be retained for a period of two years from the date of transaction.
- (6) The records referred to at items 2 to 5 above in this note shall be produced to the authorised officers whenever called upon during the course of their inspection.

By order and in the name of the Governor of Goa.

U. D. Kamat, Special Secretary (Health).

Panaji, 31st July, 2003.